Maryland Board of Pharmacy
Public Board Meeting

Agenda
December 16, 2020

Name	Title	Present	Absent
Bouyoukas, E	Commissioner		
Evans, K.	Commissioner		
Fink, K.	Commissioner		
Hardesty, J.	Commissioner/Treasurer		
Geigher, P.	Commissioner		
Leikach, N.	Commissioner		
Morgan, K.	Commissioner/President		
Oliver, B	Commissioner		
Rusinko, K.	Commissioner/Secretary		
Singal, S.	Commissioner		
Yankellow, E.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Fields, E.	Deputy Director /Operations		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Clark, B.	Legislative Liaison		
Chew, C.	Enforcement Compliance Auditor		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	**A.) K. Morgan, Board President** **B.)K. Rusinko, Secretary**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* **1. Call to Order** **2. Sign-in Introduction and of meeting attendees** – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)* **3. Distribution of Agenda and packet materials** **4. Review and approve November 2020 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata, Executive Director**	**1. Upcoming Meetings** **2. Staffing Update** **3. Vacant Board Seat** **4. Pharmacists respond to Maryland Responds Request for Volunteers** **5. NABP Innovations: Interview with Commissioner Neil Leikach** **6. Fraudulent Emails**	
B. New Business	**K. Morgan, Board President**	**1. None**	
C. Operations	**E. Fields, Deputy Director/ Operations**	**1. Procurement and Budget Updates** **a: November 2020 Financial Statements** **2. Management Information Systems (MIS) Unit Updates** **a: None**	
D. Licensing	**E. Bouyoukas, Commissioner**	**1. Unit Updates**	

<table>
<tr><th>Subject</th><th>Responsible Party</th><th>Discussion</th><th>Action Due Date (Assigned To)</th></tr>
<tr><td></td><td></td><td>2. Monthly Statistics
<table>
<tr><th>License Type</th><th>New</th><th>Renewed</th><th>Reinstated</th><th>Total</th></tr>
<tr><td>Distributor</td><td>13</td><td>1</td><td>0</td><td>1,444</td></tr>
<tr><td>Pharmacy</td><td>17</td><td>0</td><td>0</td><td>2,109</td></tr>
<tr><td>Pharmacist</td><td>51</td><td>508</td><td>0</td><td>13,013</td></tr>
<tr><td>Vaccination</td><td>50</td><td>151</td><td>0</td><td>5,047</td></tr>
<tr><td>Pharmacy Intern - Graduate</td><td>2</td><td>0</td><td>0</td><td>59</td></tr>
<tr><td>Pharmacy Intern - Student</td><td>14</td><td>10</td><td>0</td><td>769</td></tr>
<tr><td>Pharmacy Technician</td><td>78</td><td>311</td><td>1</td><td>10,794</td></tr>
<tr><td>Pharmacy Technician-Student</td><td>3</td><td>0</td><td>0</td><td>32</td></tr>
<tr><td>TOTAL</td><td>228</td><td>981</td><td>1</td><td>33,267</td></tr>
</table></td><td></td></tr>
<tr><td>E. Compliance</td><td>T. Leak, Compliance Director</td><td>1. Unit Updates
2. Monthly Statistics
Complaints & Investigations:</td><td></td></tr>
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		New Complaints – 15 • Customer Service – 1 • FDA Warning Letter, USP 797/cGMP Violations – 2 • Disciplinary Action in Another State – 1 • Unprofessional Conduct – 1 • Refusal to Fill – 1 • Medication Error – 2 • NABP VPP Compounding Issues – 3 • Inspection Issues – 3 • Fraud - 1 Resolved (Including Carryover) – 16 Actions within Goal – 9/16 Final disciplinary actions taken – 0 Summary Actions Taken – 0 Average days to complete – 0 **Inspections:** Total - 146 Annual Inspections - 74 annual 59 Narcotic Audit Follow Up Opening Inspections - 10 Closing Inspections - 1 Relocation/Change of Ownership Inspections - 1 Board Special Investigation Inspections – 1	
F. Legislation & Regulations	**B. Clark, Legislative Liaison**	**<u>Regulations</u>** None	

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		Legislation None	
III. Committee Reports **A. Practice Committee**	**Evans, K. Commissioner**	Kathleen Cook: I have a quick question in regards to the law about pre-printed prescription pads. The law states: A prescription for a controlled dangerous substance within the meaning of Article 27 of the Code, may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance. Annotated Code of Maryland, Health-General Article, Title 21-220. Preprinted prescription pads for non-controlled dangerous substances are not prohibited by law Is this the same for a pre-stamped prescription as well? I have attached a photo of the prescriber in question to verify if it is valid or not. **Proposed Response:** A pre-stamped prescription is considered a preprinted prescription as that term is used in Md. Code Ann., Health Gen. § 21-220(b). by the Board of Pharmacy and the Maryland Office of Controlled Substances Administration. For further information please contact OCSA at maryland.ocsa@maryland.gov. Mike Burns-InstyMeds: The Board of Physicians has indicated that dispensing of medication by a physician is under their oversight and jurisdiction. I am reaching out to the Board of Pharmacy to ensure that if a client of ours is proposing to implement an InstyMeds Medication Adherence System	

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		(IM-MAS) in their hospital ER that we need to work with the Board of Physicians? The system functions within the physicians dispensing model, and is not a vending machine because it is used by patients upon invitation only. Integrates the best of pharmacy practice into physician dispensing. Accuracy has been tested and confirmed. InstyMeds has been in business since 2000, and successfully operating in many states. **Proposed Response:** If the drugs are being purchased, stocked and dispensed from the machine under a physician's license, the Board of Physicians' regulations govern the transaction. Please note, however, that utilizing the physician dispensing model, the hospital pharmacy does not stock or have any oversight over the units. Kenneth Erickson – Medstar Union Memorial Hospital - (K. Evans Recused) I am requesting clarification or guidance regarding a proposed process change for dispensing of kits/trays that have been processed using our Kit Check RFID tag solution. This solution requires a Pharmacist to verify each RFID tag, attached to a product, is encoded with the correct medication, concentration, NDC, Lot#, and expiration date. The RFID scanning station then reads these Pharmacist verified products with tags to confirm that each kit or tray contains the correct medication and quantities AND that each of these products are in date and not subject to a recall. Only when the verified products in the kit/tray meet all requirements will the kit/tray be successfully completed and made available for dispensing.	

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		Our current process is to have a Pharmacist encode/verify medication stock to be used in our kits/trays for scanning by the Kit Check RFID scanning solution, have our technicians fill the kits/trays with this verified stock of medications, process the tray and receive a notice of completion when all Kit Contents meet the required needs of the kit/tray and are not expired or being recalled, and then the Pharmacist manually checks the kit/tray again and signs the printed notice of completion so the kit/tray is able to be dispense. Our findings: Because the pharmacist is responsible for the encoding and verifying of the products used with this technology solution, no product is dispensed that has not been previously verified by a pharmacist. When the pharmacists manually check these kits/trays after the RFID scanning has indicated a complete and expired med free kit/tray - they have found no incident of errors and kits/trays are signed off 100% of the time. Our request: When a successful kit/tray scan has occurred and a notice of completion is printed, we are asking that a technician is able to sign the completed kit/tray form and allow it to be dispensed without having a pharmacist manually check these again. Since all the stock has already been checked and verified by a pharmacist and the technology solution does not allow any kit/tray to be completed if there re expired or wrong meds present, we would like to have pharmacist focus on other tasks that need and require their attention. **Proposed Response:** In the situation that you have described, a final check by a pharmacist would still be required (see COMAR 10.34.34.03A(8)). Please note, however, that the Board is currently engaged in discussions of expanding its regulatory framework to allow for similar processes that will allow for technicians to perform non-clinical tasks as you have described. Wee Phung: Please allow me to describe a scenario, then ask you a question: A Maryland-licensed non-resident pharmacy is practicing strict social distancing per CDC guidelines. At the beginning of the Covid-19 period, the Maryland-licensed pharmacist of the nonresident pharmacy chose not to come to work in the pharmacy to supervise the dispensing and other daily pharmacy operations, because he lives with a high-risk family member.	

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		However, he counsels patients on their prescriptions via a HIPAA-secured phone and computer system in his home. The nonresident pharmacy does not have another Maryland-licensed pharmacist on staff. Since the Maryland-licensed pharmacist is not onsite, may the resident state-licensed PIC temporarily assume PIC duties for Maryland during this public health emergency period, and if so, should she send a notification to the board? If not, do you have other advice to give? I would appreciate you referencing legislature sections in your answers. **Proposed Response:** Maryland regulation 10.34.37.04B(2) requires that the Maryland-licensed pharmacist on staff at a nonresident pharmacy and designated as responsible for pharmaceutical care provided to Maryland patients must be regularly available on-site "as-needed" to provide care for Maryland patients. What constitutes "as-needed" is left to the professional judgment of the pharmacy and the Maryland pharmacist. Please note, however, that the designated Maryland pharmacist remains *responsible* for all pharmaceutical care provided to Maryland patients by the pharmacy, regardless of whether the designated pharmacist personally provided the care to the patient. Michael F. Conti: Maryland State Board of Nursing: I have a client that will be completing her course of study to be a nurse practitioner in December. She is currently licensed as an RN in Maryland. After graduation as a nurse practitioner, she would like to open a business where she would give IVs that consist of non-prescription drugs like vitamin C, B12, and saline. I've reviewed the COMAR for a nurse practitioner's scope of practice and the text of House Bill 999 and Senate Bill 723 (2015) and have a few questions: 1. COMAR 10.27.07.02(B)(7) states that an applicant for certification as a nurse practitioner has not been certified by the Board or any other Board of Nursing must designate a mentor for 18 months. Does this mean that if an applicant for certification as a nurse practitioner has been a registered nurse in Maryland the applicant does not have to designate a mentor? Or do all nurse practitioner applicants that are applying for the first time ever to be	

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		certified as a nurse practitioner in Maryland have to designate a mentor, regardless of whether they have been an RN? 2. Can a nurse practitioner delegate to a RN or LPN the tasks of preparing and administering an IV to a person that contains vitamins such as vitamin C or B12? What type of supervision level does a nurse practitioner have to provide to an RN if delegating any type of task? 3. Can an RN implement standard protocols that have been developed by a nurse practitioner, for example, a nurse practitioner develops protocols for when vitamin C is delivered to a person by IV- can an RN carry out those protocols without supervision? **Proposed Response:** The Board of Pharmacy does not have any jurisdiction over the practice of a nurse practitioner; however, in the practice of pharmacy, the practice that you have described would be considered infusion therapy (see COMAR 10.27.20.02B(14)). **Stephanie Oster: Medstar Health: (K. Evans recused):** If we were to find that we need to close some of our locations temporarily due to staffing shortages from COVID-19 is that something the BOP allows and what are the requirements to do so? We are trying to figure out if this is something we may need to look at for our chain. My main questions are around the notification piece as well as what happens with the current inventory in the pharmacy that may temporarily close? **PLEASE NOTE THAT THIS QUESTION IS A HYPOTHETICAL QUESTION AND DOES NOT REFLECT AN IMMEDIATE NEED TO CLOSE BY THE PHARMACY IN QUESTION.** **Proposed Response:** Please see the Board's March 17 guidance regarding closures and changes to hours of operation during the COVID-19 pandemic. The Board will not enforce the 30-day notice requirement during the state of emergency; rather, the Board requires that pharmacies provide advance notice as soon as practicable if an establishment location is forced to change its hours or temporarily close.	

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		With respect to your question about inventory, the outcome will need to be determined on a case-by-case basis, dependent on the facts of the situation.	
B. Licensing Committee	**, Chair**	**1. Review of Pharmacist Applications:** **a.** **#124987 -** Applicant is requesting an extension of her BOP application. COVID has forced her to reschedule her exams. ***Committee recommendation: Deny extension, applicant is welcomed to reapply when application expires.*** ***b.*** **#123883 -** Applicant is requesting an extension of her MPJE and NAPLEX eligibility. Her ability to sit for the exams has been affected by COVID closures and preparing for the exams have been hindered by health complications. ***Committee recommendation: Approve extension for 6 months, must reapply*** ***c.*** **#119808 -** The Board has received a request from NABP to approve for the applicant to retake the NAPLEX exam for an 11th attempt. ***Committee recommendation: Approve, must reapply if application expires*** ***d.*** **#127621 -** Applicant is requesting an extension of the expiration date of her NAPLEX score. ***Committee recommendation: Approve extension for 6 months*** ***e.*** **#125002 -** Applicant is requesting for approval to take the MPJE for an eighth time.	

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		Committee recommendation: Approve, will need to reapply after March. **f.** **#123951 -** Reciprocity applicant is requesting an extension of his MPJE eligibility for a few months due to the current circumstances. ***Committee recommendation: Approve extension for 6 months, will need to reapply*** **g.** **#127088 -** Applicant is requesting approval to take the MPJE for a 6th attempt. ***Committee recommendation: Approve*** **h.** **#122015 -** Applicant is requesting extension of Board application and NAPLEX score. NAPLEX score expires 12/03/2020 ***Committee recommendation: Approve score extension for 6 months, must reapply*** **2. Review of Pharmacy Intern Applications: NONE** **3. Review of Pharmacy Technician Applications: NONE** **4. Review of Distributor Applications: NONE** **5. Review of Pharmacy Applications: NONE** **6. Review of Pharmacy Technicians Training Programs: NONE** **7.** CE Approval Requests: **a.** **MBF** (MBF 1, MBF 2, MBF 3, MBF 4, MBF 5, MBF 6, MBF 7, MBF 8, MBF 9) - 10th Annual Pain Care Skills Training	

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		Committee recommendation: Approve for 15 hours **8. New Business:** **a.** **SS -** Technician in training is requesting an extension due to COVID 19 of the 6-month registration requirement to complete the 160 hours. ***Committee recommendation: Extend for 3 months*** **b.** **Steve Siegel** /Best Pet Rx - Company is requesting approval to use the Virginia Board of Pharmacy inspection report in lieu of submitting a VPP inspection. ***Committee recommendation: Will accept the VA Board of Pharmacy inspection*** **c.** **Bonnie Scott** – Is a contract manufacturer that does not distribute into Maryland required to have a permit? Tabled from November 2020 Board Meeting ***Committee recommendation: When Company A holds the FDA marketing authorization for the drug, then it would need a permit in Maryland. When Company A's customer hold the FDA marketing authorization, then Company A does not need a permit as long as they are not a part of distribution into Maryland.*** **d.** **Joseph Acierno** - Inquirer is requesting guidance regarding dispensing into Maryland: The inquiry below was initially sent to the Office of Health Care Quality, Maryland Department of Health, requesting the need for a Residential Service Agency License. They recommended that I follow up with the Board of Pharmacy. As background, Amber Specialty	

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		Pharmacy has brick and mortar locations in Nebraska and New York. Those pharmacies hold non-resident Maryland pharmacy licenses allowing us to serve the citizens of Maryland. There are two issues for your consideration: 1. If Amber Specialty Pharmacy dispenses, what is considered a percutaneous nerve field stimulator, to a Maryland resident, would this require additional licensure, other than a pharmacy license, in the state of Maryland? In most cases, the prescribed device would be dispensed to the prescribing health care professional to provide to the patient. This item would be delivered via common carrier. 2. If Amber Specialty Pharmacy provides/dispenses infusion pumps, tubing and related supplies to a patient as part of infusion therapy, would this require additional licensure, other than a pharmacy license, in the state of Maryland? These items would be delivered via common carrier. ***Committee recommendation: Regarding scenario #1 If over 5% of annual sales a Distributor permit is needed. Regarding #2, only the pharmacy permit is needed*** ***e.*** **Prescription Drug Monitoring Program -** The Office of Provider Engagement and Regulation (OPER) is statutorily required to consult with the Technical Advisory Committee (TAC) to support the Prescription Drug Monitoring Program's (PDMP) quantitative data analysis and utilize their clinical expertise. According to Health General §21-2A-07, the TAC is responsible for providing clinical guidance and interpretation of PDMP data to identify possible violations of law or possible breaches of professional standards within PDMP data. The TAC	

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		consists of a voluntary group of nine providers including a pharmacist, as well as other providers. Dr. Nadeem Aslam currently fills the pharmacist seat. OPER is reaching out to the Maryland health licensing boards requesting continuing education credits for TAC members' time and commitment to PDMP activities. Most TAC members contribute ~2 hours per quarter between meetings and review of PDMP data. OPER staff track TAC member participation and could offer documentation to the Board. The TAC serves an incredibly important role for the PDMP. The TAC ensures that prescribers receive clinically relevant information in the educational letters and helps the PDMP identify specific metrics that guides educational outreach. Would the Board of Pharmacy offer continuing education credits to relevant TAC members for their time and efforts supporting the PDMP? ***Committee recommendation: Under our current regulations we could not allow for CE's to be counted.*** **f.** **Flywheel Healthcare**- Will the Board accept a NABP Supply Chain Inspection in lieu of a VAWD inspection for a relocating Distributor? ***Committee Recommendation: They do need an inspection; the Board can accept pending VAWD accreditation. Will be required to have a background check if staff has changed or results are not dated within the last 6 months.***	
C. Public Relations Committee	**E. Yankellow, Chair**	**Public Relations Committee Update:**	

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D. Disciplinary	**J. Hardesty, Chair**	**Disciplinary Committee Update**	
E. Emergency Preparedness Task Force	**N. Leikach, Chair**	**Emergency Preparedness Task Force Update**	
IV. Other Business & FYI	**K. Morgan, President**		
V. Adjournment	**K. Morgan, President**	**A. The Public Meeting was adjourned.** **B. K. Morgan convened a Closed Public Session to conduct a medical review committee evaluation of confidential applications.** **C. The Closed Public Session was adjourned. Immediately thereafter, K. Morgan convened an Administrative Session for purposes of discussing confidential disciplinary cases.** **D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Closed Public Session and the Administrative Session.**	